Appendix A: Example of Weighted Lottery Policy for Fair Allocation of Medications to Treat COVID-19[i]

This example has been provided by the State of Pennsylvania "Ethical Allocation Framework for Emerging Treatments of Covid-19." [ii]

Introduction: The purpose of this appendix is to provide hospitals step-by-step instructions to conduct a weighted lottery allocation policy. The following groups will receive heightened priority: 1) individuals from disadvantaged areas, defined as residing at an address with an Area Deprivation Index (ADI) score of 8 to 10 (range 1-10; with higher numbers meaning worse deprivation); and 2) essential workers, defined by the Commonwealth of Pennsylvania list of essential businesses that are required to continue physical operations during the pandemic. Individuals expected to die within a year from an end-stage condition should not be excluded from access to the weighted lottery but should receive lower priority than individuals who do not have an end-stage condition. This prioritization methodology creates meaningful access to all patients, maximizes community benefit, and proactively mitigates disparities, all consistent with the ethical goals of the framework.

Preliminary steps: The following three steps should be completed at the time that COVID-19 treatment is allocated to a hospital.

1. **Determine the number of available courses of the COVID-19 therapy.** This information will be provided by the Commonwealth of Pennsylvania or the agency responsible for distribution.
2. **Estimate the number of eligible patients over the time period in question for which the drug is allotted.** To accomplish this, first determine the average number of patients admitted daily over the last week who met eligibility criteria for the COVID-19 medication. Next, calculate the number of days the supply of medication is expected to last based on dosage, and the number of eligible patients.
3. **Determine the chances for each eligible "general population" patient to receive the drug.** These chances are determined by dividing the number of available courses of medication by the projected number of eligible patients. For example, if there are 25 courses of drug available and 100 patients expected to be eligible over the time period in question, the "general population" chances to receive the drug are 25 out of 100 (25%). This number will be used in step 4 below to calculate the chances for other populations.

NOTE: There may be uncertainty or changes in the number of treatment courses available, the time period that the supply of medication needs to last, or the average number of eligible patients per day. It is appropriate to recalculate the lottery chances as new information becomes available about these parameters.

Daily Steps to Allocate Scarce COVID-19 Medications

1. **Proactively identify eligible patients with COVID-19.** Hospitals should take proactive steps to identify eligible patients as discussed previously in this framework, rather than placing this burden solely on treating physicians, who may not be aware of the availability of the scarce drug for their patient. This approach increases the chances that all eligible patients will be offered the opportunity to be in the lottery. The Crisis Triage Officer Team may be able to screen each COVID-19 patient in the hospital, or to use EHR-based screening mechanisms to identify patients with COVID-19 who are eligible to receive the scarce therapy. The optimal approach will depend on each hospital's resources.

2. **Confirm each COVID-19 patient's eligibility with the attending physician.** The Crisis Triage Officer Team should contact the attending physician of each patient with COVID-19 to confirm eligibility. This conversation should ascertain the following: 1) that the patient meets inclusion criteria to receive the scarce drug; 2) that the patient does not meet any clinical exclusion criteria for the scarce drug; and 3) the patient consents to receive the drug. Consent may also take place after the patient is selected to receive the drug in the lottery.

iii This Appendix represents one suggested approach, but it is not the only approach to satisfy the ethical goals identified by Pennsylvania's Ethical Allocation Committee.

3. **Determine patient's characteristics relevant to the weighted lottery.** The Crisis Triage Officer Team should assess the three characteristics relevant to the weighted lottery:

a. Is the patient from a disadvantaged community? The allocation team should determine whether the patient resides in a disadvantaged community, defined as their residential address being in an area with score of 8, 9, or 10 on the Area Deprivation Index. This can be determined by entering the patient's address in the Neighborhood Atlas **website** under the "mapping" tab.

(https://www.neighborhoodatlas.medicine.wisc.edu/)

b. Is the patient an essential worker? In conjunction with the patient's attending physician, the Crisis Triage Officer Team should determine whether the patient meets the Commonwealth of Pennsylvania's definition of an essential worker, as specified in this **Industry Operation Guidance document**

(https://www.scribd.com/document/452553026/UPDATED-8-45pm-May-11-2020-Industry-Operation-Guidance)

c. **Is the patient expected to die within a year from a chronic, end-stage condition?** In conjunction with the patient's attending physician, the Crisis Triage Officer Team should determine whether the patient is likely to die within a year from underlying condition(s) despite successful treatment of the COVID-19 infection. The objective medical evidence supporting this determination should be documented. If needed, specialist consultation should be sought (e.g. oncology, geriatrics, palliative care) to ensure the decision is an objective medical determination. If physicians are uncertain whether the patient is likely to die within a year, they should err on the side of assuming that the patient will survive for more than a year.

4. Conduct the lottery for each eligiblepatient.

a. The first step is to determine the lottery threshold for each eligible patient. Table 1 contains a summary of the adjusted chances for each patient group, which are based on the chances of a "general community" member, with adjustments for priority considerations. Table 2 provides an example of this when there are only enough courses of treatment to treat 25 out of 100 (i.e., 0.25) general community members.

Table 1. Weighted chances to receive treatment for each patient group

Group	**Chances to receive treatment**
General community chances	Number of available treatment courses/ Number ofeligiblepatientsinthedetermined time period
Disadvantaged community member	1.25 x (general community chances)
Essential worker	1.25 x (general community chances)
Death likely within 1 year	0.5 x (general communitychances)
Disadvantaged community member + Essential worker	1.5 x (general community chances)
Disadvantaged community member + death likely within 1 year	0.75 x (general communitychances)
Essential worker + death likely within 1 year	0.75 x (general communitychances)

Table 2. Example when the chances for treatment with the scarce COVID-19 treatment for the general community are 25 out of 100

Group- Individuals who are…	**Chances to receive treatment**
General community members	0.25 (25 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10	1.25 x 0.25 = 0.31 (31 out of 100)
Essential workers	1.25 x 0.25 = 0.31 (31 out of 100)
Expected to die within a year from an end-stage condition	0.5 x 0.25 = 0.13 (13 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10 **AND** are Essential workers	1.5 x 0.25 = 0.38 (38 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10 **AND** Expected to die within a year from an end-stage condition	0.75 x 0.25 = 0.19 (19 out of 100)

Essential worker **AND** Expected to die within a year from an end-stage condition	0.75 x 0.25 = 0.19 (19 out of 100)

1. **The second step is to randomly select a lottery number for each eligible patient.** This can be done with a random number generator that are readily available online. The range of the lottery should be set to "1 to 100." The drawing of each patient's lottery number should be witnessed by two individuals and recorded. **Each patient is entered into the lottery only once, not every day that they are eligible to receive the scarce drug.** The only time a lottery shoul be re-run is if there is an abrupt, significant change in supply of the scarce drug

c. **Determine whether each patient's lottery number is within the range to offer the scarce drug.** For example, if the lottery chances for the patient is 31 out of 100 and the patient's randomly drawn lottery number is ≤ 31, they should be offered the scarce drug. If the lottery number is >31, then they should not be offered the scarce drug.

5. **Inform the patient's attending physician of the lottery result.** Immediately after the weighted lottery is conducted, the allocation team should inform the patient's attending physician of the lottery results (i.e., whether the patient will be offered the treatment).

6. **If patient is to receive the drug, contact the pharmacy to provide the patient-specific medication order and authorize release of drug.** Facilities may have different ways to order the medication, because the drug may not be made readily available to order by all prescribers.

7. **Documentation:** The allocation team should document that each of the steps above was performed for each eligible patient. Two members of the allocation team should witness and attest to the correct conduct of the lottery, and should record each patient's lottery number, as well as each patient's lottery threshold to receive the scarce COVID-19 therapy.

i. D. Hinton, "Response to Gilead Sciences Inc's Request for Emergency Use Authorization of Remdesivir For the Treatment of Hospitalized 2019 Coronavirus Disease Patients," U.S. Food and Drug Administration, May 1, 2020, Page1. https://www.fda.gov/media/137564/download

ii. Pennsylvania Department of Health. Ethical Allocation Framework for Emerging Treatments of Covid-19. https://www.health.pa.gov/topics/disease/coronavirus/Pages/Guidance/Ethical-Allocation-Framework.aspx. Accessed 11/6/20.